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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/690,685	10/22/2003	Shigeru Nemoto	KIT02.001DV2	6145
20995	7590	10/18/2006	EXAMINER	
KNOBBE MARTENS OLSON & BEAR LLP			HUH, BENJAMIN	
2040 MAIN STREET			ART UNIT	
FOURTEENTH FLOOR			PAPER NUMBER	
IRVINE, CA 92614			3767	

DATE MAILED: 10/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/690,685	NEMOTO, SHIGERU	
	Examiner	Art Unit	
	Benjamin Huh	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 August 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 4-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 4-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :2/21/06; 4/25/06; 5/19/06; 8/2/06.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 & 4-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Botich et al (US Patent No. 5188599). Botich et al discloses a retractable needle system as seen in figures 1-6 comprising a syringe barrel 55 with a flange 79 having a projection 83 on a rear surface thereof, also see col. 9 lines 41-50, also wherein the opposite the side of the projection would touch the front wall of the groove; the flange being inherently capable to be held by a flange insertion groove so as to fix the syringe barrel; the projection 83 being formed and being inherently capable to be inserted into a flange insertion groove on a cylinder holder and mounted in a use position, the projection 83 has a narrower width toward the tip as can be seen in figure 1; and a tip of the projection 83 being inherently capable of being compressed whereby the flange fully capable of being fitted and fixed into a flange insertion groove due to the size and shape of the flange not severely differing from the normal sizes and shapes of a syringe flange, and due to its ability to perform in the environment, and the projection 83 and the flange 79 together are inherently capable of being inserted into a flange insertion groove

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and the tip of the projection 83 is capable of being compressed so as to press the flange against a front sidewall surface of the flange insertion groove in a use position due to the size and shape and ability to perform in the environment.

With regards to claim 4, the flange has a two flange cut portions symmetrically positioned in the flange opposite to each other seen in figures 1-3.

With regards to claim 5, the flange has an even number of projections 83 symmetrically disposed to one another on the flange over a portion of the flange where the two flange cut portions are not provided as can be seen in figure 1 where there is a total of 6 projections with an even amount on each side of the flange.

Claim 9 is rejected under 35 U.S.C. 102(b) as being anticipated by Bitdinger et al (US Patent No. 5667495). Bitdinger discloses a cylinder holder 10 seen in figures 1-20 comprising a flange insertion groove 31 for holding a syringe barrel; a projection 38 on an inner wall surface of the flange insertion groove to be contacted with a rear surface of a flange of the syringe barrel; the projection 38, which is extended from the rear inner wall in the direction of a front wall of the flange insertion groove, being so formed that when the flange is inserted in the flange insertion groove and mounted in a use position, the projection compresses the flange, thereby the flange is fitted and fixed in the flange insertion groove. The finger grip is inherently capable of holding a syringe barrel as well as fitting and fixing the flange of the syringe barrel in the flange insertion groove due to its shape, size, and ability to work in the necessary environment.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bitdinger (US Patent No. 5188599) as applied to claim 9 and further in view of Stanners (5593391). Bitdinger discloses a syringe barrel 14 with a flange 22 to be held by the flange insertion groove. Now even though the syringe barrel in Bitdinger does not disclose a concave portion attention is directed to Stanners. The Stanners reference discloses a syringe barrel comprising a concave portion formed on the surface of the flange in figures 3 & 15 and it would be obvious to one of ordinary skill in the art at the time of the invention to incorporate a concave portion to the surface of the flange of Bitdinger in order to allow a more secure grip of the projections to the syringe barrel to prevent movement of the syringe barrel.

Claims 6-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Botich et al (US Patent No. 5188599). Botich et al discloses an injection system comprising a syringe barrel comprising a flange having a projection being inherently capable of being inserted into a flange insertion groove. Even though the Botich system does not explicitly state the projection to have a pyramid-like shape or a conical shape it

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would be obvious to one of ordinary skill in the art at the time of the invention to have a pyramid-like shape or conical shape or any other desired shape since applicant does not state the advantages of such shapes and therefore the projections seen in Botich are seen to have an equivalent function, way, and result as the pyramid or conical shape, attention is also directed to MPEP 2144 Section IV B, In Re Dailey for obvious design choice in shape.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Botich et al (US Patent No. 5188599) in view of Bitdinger et al (US Patent No. 5667495). Botich et al discloses an injection system comprising a syringe barrel comprising a flange having a projection being inherently capable of being inserted into a flange insertion groove. Even though Botich does not disclose a cylinder holder comprising a flange insertion groove for holding the syringe barrel and a concave portion formed on an inner wall surface of the flange insertion groove to be contacted with the rear surface of the flange of the syringe barrel; whereby, the concave portion is engaged with the projection on the rear surface of the flange when the syringe barrel is mounted in a use position attention is directed to Bitdinger. The Bitdinger reference discloses a cylinder holder 10 in figures 1-20 comprising a flange insertion groove 31 for holding the syringe barrel, and a concave portion (see col 4. line 60 – col 5. line 7) formed on an inner wall surface of the flange insertion groove to be contacted with the rear surface of the flange of the syringe barrel; whereby, the concave portion is inherently capable of engaging the

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projection on the rear surface of the flange when the syringe barrel is mounted in a use position due to the size, shape, and ability to work in the environment.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Botich et al (US Patent No. 5188599) in view of Ritz (US Patent No. 3438549) or Tompkins (US Patent No. 4030498). Even though Botich does not disclose a pre-filled syringe attention is directed to Ritz or Tompkins. The Ritz and Tompkins references both disclose pre-filled syringes and it would be obvious to one of ordinary skill in the art at the time of the invention to have the syringe to be pre-filled for ease of use and to save time also attention is directed to Tompkins col 1. lines 15-17 where it states that "... many syringes are pre-filled ...".

Response to Arguments

Applicant's arguments filed 8/2/06 have been fully considered but they are not persuasive.

Applicant argues that Botich does not disclose a projection on the rear surface of the flange or the front surface of the flange to touch the front wall of the groove, the examiner disagrees. The applicant does not clearly claim which side of the flange is deemed to be the rear surface therefore it is the examiner's position that the distal surface(surface closer to the needle) of the flange is the rear surface and therefore Botich still encompasses the limitations of the claim. Also, since the walls of the groove

of the holder is not clearly defined the wall that the front surface of the flange would indeed touch the front wall of the groove.

Applicants arguments with respect to Botich et al in view of Bitdinger et al, Botich et al alone, and Botich in view of Ritz for 103(a) are addressed by the arguments in view of Botich presented above.

Applicant's arguments with respect to claim 9 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Burke (US Patent No. 6457606) discloses a cylinder holder seen in figures 1-3 for accepting a syringe barrel. Miller et al (US Patent No. 4540405) also discloses a cylinder holder as seen in figures 1 & 2. Gagnieux et al (US Publication No. 2003/0050607A1) discloses a syringe barrel with projections and a cylinder holder for the syringe barrel in figures 1-10. Vetter et al (US Patent No. 6296625) discloses a cylinder holder with a projection on an inner wall surface of the flange insertion groove as can be seen in figures 1-5. Bitdinger et al (US Patent No. 5667495) also discloses the cylinder holder to have projections in the flange insertion groove (see col. 6 line 47 – col 7. line 10). B. Braun Nelsungen (DE 91 05 980.1) also discloses a syringe barrel with projections on the flange.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Benjamin Huh whose telephone number is 571-272-8208. The examiner can normally be reached on M-F: 9:00 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

BHH

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER

Kevin C. Sirmons